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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,335	12/17/2001	Eva Redei	053662-5002-01	4164

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EXAMINER

LI, QIAN J

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,335

Applicant(s)

REDEI ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1, 2, and 55 are drawn to a WMI rat, and an isolated cell of WMI rat. Classified in Class 800, subclass 8, and class 435, subclass 325.
- II. Claims 3, 4, and 56 are drawn to a WLI rat, and an isolated cell of WLI rat. Classified in Class 800, subclass 8, and class 435, subclass 325.
- III. Claims 5-18 are drawn to a method of identifying a compound capable of treating a behavioral disorder in a mammal using a WMI or a WLI rat. Class 424, subclass 9.2.
- IV. Claims 19-32, and 59-61 are drawn to methods of isolating a nucleic acid associated with a behavioral disorder in a mammal using WMI and WLI rat. Class 435, subclass 91.2.
- V. Claims 33-36, 62, and 63 are drawn to a nucleic acid associated with a behavioral disorder in a mammal, and an antisense nucleotide corresponding to the nucleic acids. Class 536, subclass 23.1.
- VI. Claims 37-42, and 46-51 are drawn to methods of isolating a polypeptide associated with a behavioral disorder in a mammal using WMI and WLI rat. Class 435, subclass 69.1.
- VII. Claims 43, 44, 52, and 53 are drawn to a polypeptide associated with a behavioral disorder in a mammal, and an antibody that specific binds to the polypeptide. Class 530, subclass 350.

VIII. Claims 45 and 54 are drawn to a compound that modulates the activity of a polypeptide associated with a behavioral disorder in a mammal. Classification is to be determined depending on the nature of the compound.

IX. Claims 57 and 58 are drawn to a method of identifying a compound that regulates expression of a nucleotide sequence associated with depression or a behavioral disorder in a cell in vitro. Classified in class 435, subclass 91.1.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II, V, VII, VIII, and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups II, V, VII, VIII, and I are drawn to a different product, i.e. a rat, a nucleic acid, a polypeptide or a compound. The different products are distinct in chemical structure and biological function as well as modes of operation when used as therapeutic and diagnostic agents. For example, a WMI rat exhibit a distinct behavior pattern and different genetic make-up compared to a WLI rat as taught in the specification.

Inventions IV, VI, IX and III are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, groups IV, VI, IX and III are drawn to different methods of identifying compounds, isolating nucleic acids, and isolating polypeptides. Each of the groups differs in the starting materials used in the process (cells or different animals), method steps in

obtaining the different materials, and means for measurement, such as behavior tests, or nucleic acid expression test. The different methods require distinct technical considerations and search criteria.

Inventions IV and V, or VI and VII are related as process of making and product made, respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of groups IV and VI could be used to identify many structurally different nucleic acids and polypeptides, and the substance of groups V, VII could be used in different processes, such as diagnosis of a disease and treatment of a disease.

Inventions III, IV, VI, and I/II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of group III could be practiced with either a WMI or a WLI rat, and a WMI rat could be used in a different process such as indicated in groups III or IV or VI; in production of a protein, and in breeding.

The differences of the Inventions I-IX are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search

criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Invention III is directed to a method of identifying a compound using a rat. If invention III is elected, further election of a particular species of rat, i.e. a WMI or a WLI rat, is necessary.

Invention V, VII, and VIII are directed to nucleic acids and polypeptides associated with a behavior disorder or compounds that modulates the activity of a polypeptide. The claims may encompass structurally and functionally distinct nucleic acids, polypeptides, and compounds. If one of the invention groups V, VII, and VIII, is elected, further election of a particular nucleic acid, a particular polypeptide, or a particular compound is necessary. And the election may be a species election or a different invention depending on the nature of the encompassing nucleic acids, polypeptides, and compounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5-54 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li
Examiner
Art Unit 1632

QJL
February 27, 2003